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Health State Utility Assessment for Breast Cancer

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ABSTRACT

Objectives: 1) To develop both English and Chinese versions of the descriptions of health states describing different stages of breast cancer and different adverse effects related to tamoxifen and aromatase inhibitors for breast cancer and 2) to elicit individuals' preferences for these health states from a group of oncology nurses. **Methods:** Twenty hypothetical health states and their descriptions were developed on the basis of literature review and oncology expert panel reviews. Health state utilities were obtained from 20 oncology nurses by using the visual analogue scale and standard gamble methods. After recalibration, the adjusted utility scores were on a scale of 0 (dead) and 1 (perfect health). **Results:** The health states developed represented different disease stages and the presence and type of treatment side effects in breast cancer. For each health state, various general health-related quality-of-life domains, such as pain/discomfort and ability to work, were included in the descriptions, along with a state-specific description. The mean utility score of respondents' "current health" was greater than 0.9, while mean adjusted visual analogue scale–derived utility scores ranged from 0.256 to 0.860 and median adjusted standard gamble–derived utility scores ranged from 0.284 to 0.673. Among the side effects evaluated in the "no recurrence" health state, ischemic cerebrovascular events, pulmonary embolism, and spine fracture had the greatest utility detriment. **Conclusions:** The study results indicate the value that individuals place on the avoidance of disease progression and the side effects of hormonal therapies in breast cancer. The health state descriptions developed can be used in future research to obtain society's utilities for use in a cost-utility analysis.

Keywords: breast cancer, standard gamble, utility, VAS.

Introduction

Breast cancer is one of the world's leading malignancies, and billions of dollars are spent each year on its treatment [1–3]. Approximately two-third of all breast cancer patients are diagnosed with hormone receptor (HR) positive breast cancer [4]. Hence, endocrine therapy, along with other treatment strategies such as surgery and chemotherapy, is one of the main treatment modalities used in patients with early stage HR positive breast cancer. For the past few decades, tamoxifen has been advocated as the gold standard of hormone treatment. More recently, for postmenopausal HR positive breast cancer patients, third-generation aromatase inhibitors such as anastrozole can serve as an alternative treatment option. In choosing the most appropriate therapy for postmenopausal HR positive breast cancer, in addition to effectiveness, factors such as the cost and adverse effect profile of hormonal agents and patients' health-related quality of life (HRQOL) are important and need to be carefully considered.

One way to incorporate these multiple factors into an economic evaluation is through cost-utility analysis, which compares the cost per quality-adjusted life-year between different treatment strategies. As an essential component of cost-utility analysis, utility scores can be obtained by eliciting individual preferences for health states or outcomes by using direct valuation methods such as the standard gamble (SG), time trade-off, or visual analogue scale (VAS). Utilities can also be obtained indirectly by mapping the scores from a disease-specific HRQOL measure, which are more sensitive than generic ones but do not have utility scoring systems, onto a preference-based generic measure such as the EuroQol five-dimensional questionnaire. Currently, utility data that reflect the preferences of the community for breast cancer–related health states are not available in Singapore.

Because there is no appropriate disease-specific HRQOL measure that can be used for all the health states assessed and because Singapore-specific population-based values for the EuroQol five-dimensional questionnaire are not available, the direct valuation approach was adopted in this study. We aimed to develop both English and Chinese versions of the descriptions of health states describing different stages of breast cancer (no recurrence, local recurrence, distant recurrence) and of different adverse effects related to hormonal therapies for breast cancer, specifically tamoxifen and aromatase inhibitors. In addition, the preferences for each of these health states were elicited from a group of oncology nurses.

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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Methods

Development of health states

To facilitate the development of the first draft of the health states, a targeted literature review was conducted to identify the adverse effect profiles of hormonal therapies and their impact on various HRQOL aspects. Validation of the health state descriptions was conducted by a group of experts comprising breast oncologists and experienced oncology nurses.

Literature review

After the literature review, the following adverse effects resulting from adjuvant hormone therapy were identified and included for evaluation: fractures, vaginal bleeding, venous thromboembolism, cataracts, ischemic cerebrovascular events, musculoskeletal disorders, hot flushes, and endometrial cancer, which are all significant adverse effects of anastrozole and tamoxifen reported in the Arimidex, Tamoxifen, Alone or in Combination trial [5,6]. Validated HRQOL instruments, namely, the European Organisation for Research and Treatment of Cancer breast cancer-specific and the Functional Assessment of Cancer Therapy-Breast quality-of-life questionnaire were used as references [7,8] in description development. Efforts were made to ensure that both the pertinent characteristics and the degree of detriment that patients may experience during their course of cancer therapy were accurately incorporated into the respective health state descriptions.

Health state description validation

The drafted health state descriptions underwent content validation by an expert panel, which consisted of three breast cancer oncologists and four oncology nurses who had at least 2 years of experience in oncology. The health state descriptions were reviewed and modified to ensure their accuracy with regard to symptoms, patients' feelings, and the level of detriment in each HRQOL aspect included.

No major amendments were required, and it was generally agreed that the drafted health state descriptions were comprehensive. Feedback from oncologists was minor and led to minor modifications of some descriptions for clarity. An additional domain on sleep was suggested by the nurses, and upon further literature review, this domain was added to the final health state descriptions. A second round of validation with the same expert panel was conducted, and then the health state descriptions were finalized.

Development of the Chinese version of the health state descriptions

A Chinese version of the health state descriptions was developed through forward and backward translation. The forward translation was done by the study investigators (all were bilingual and two had research experience in translation), and back translation was performed by a bilingual PhD pharmacy student who did not see the original English version. After the back translation, the original and back-translated health state descriptions were compared, discrepancies were identified, and the Chinese translated version was modified accordingly. Several iterations of the process occurred before no difference was considered major by the study investigators.

Health state utility measurement

Participants

A pilot study was conducted with two pharmacy PhD students and one research assistant to identify any potential problems or further clarification needed in interview instruments and procedures. No issues arose from the pilot study; therefore, no revision was made.

The main study was conducted at the National Cancer Centre Singapore, the largest ambulatory cancer center in Singapore that treats approximately 70% of all cancer patients. This study was approved by the Singhealth Centralized Institutional Review Board. Face-to-face interviews of oncology nurses were conducted by a trained research assistant in November 2010. Inclusion criteria for participants were 1) 21 years of age or older, 2) able to comprehend either English or Mandarin, and 3) a minimum of 2 years of experience in oncology. All respondents received a nominal fee of S $50 as compensation for study participation.

Utility measurement procedures

In the interview, respondents were first required to complete a sociodemographic questionnaire and were then instructed in the VAS and SG procedures [9] to measure their preference for the "dead" state, current health, and each of the 20 hypothetical health states of breast cancer.

The descriptions for each health state were presented to the respondents on a laminated card. The cards were labeled with a letter of the alphabet on the back and no headings were provided to denote what the health states were. Respondents were asked to read and comprehend all the health state cards. The trained interviewer explained to the respondents about the different colored text on the cards and their respective meanings. Text in dark purple presented aspects of health that were specific to that particular health state. In contrast, text in orange and black presented the common aspects of health in most health states, but the level of detriment in these aspects could differ among different health states. After explanation, the respondents were asked to rank the health states provided in the descending order according to their preferences along with a VAS (i.e., feeling thermometer) anchored by the health state they considered the worst at the bottom (0 point) and perfect health at the top (100 points). Respondents were then asked to give all the other health states a value between 0 and 100. If respondents were unable to differentiate between two health states, that is, if they felt that two health states were similar, the two could be given the same value.

With the SG, to aid in understanding, respondents were shown a color schematic diagram on a computer screen. For each health state under evaluation, the respondents were asked to choose between three options [10]: 1) living in that particular health state with certainty for the rest of their lives, 2) having a 50-50 chance of living in perfect health or in the worst health state (HSw), and 3) determining that the first two choices were equal. Once the respondent had made an initial decision, the chance probability (p) was varied systematically in increments of 5% until the respondent switched between the first two options or selected option 3. The same SG procedure was performed to obtain the utility score for the "dead" state except that if the respondents considered being dead worst than HSw, they were asked to choose between living in HSw or accepting a gamble between perfect health and being dead instead. A probability wheel was used as a visual aid to help the respondents more easily understand the probabilities presented [11].

Statistical analysis

Demographic data were summarized with means and SDs for continuous variables and percentages for categorical variables. In the VAS, if "dead" was placed at the 0 of the scale, the utility score for each of the other health states was the scale value of its placement. If being dead was considered better than HSw and placed at some point between 0 (HSw) and 1 (perfect health), scale recalibration was needed. The adjusted score was equal to

VAS_{adj} = (raw score − score_dead)/(1 − score_dead)

where score_dead is the scale placement of the "dead" state. After recalibration, the adjusted scores can be conceptualized on a scale of 0 (dead) and 1 (perfect health). Similar adjustment was performed for the SG utility scores if HSw was judged to be the worst. In the SG, however, if being dead was considered worse than HSw, the adjusted score was equal to

$$SG_{adj} = \text{raw score} + (1 - \text{raw score})\text{sg\_HSw}$$

where sg_HSw is the probability (p), that is, the utility score, obtained for HSw. Mean and median were used to summarize utility scores derived from VAS and SG procedures. All statistical analyses were conducted by using the Statistical Package for the Social Sciences, version 18 (SPSS, Inc., Chicago, IL).

Results

Health state descriptions

Various general HRQOL domains such as pain/discomfort, lifestyle, daily activities, ability to work, relationships with family and friends, presence of optimal approach to life, problems with memory, and future perspective in both work and personal life were included in the health state descriptions. Different levels of detriment in each domain were used to reflect the differences among the health states. In addition to descriptions of general domains, for each health state, a health state–specific description was also included. Examples include "You develop a blood clot in the blood vessels of your leg(s) and it causes pain and swelling" for health state F (no recurrence with deep vein thrombosis) and "You develop clouding of the lens inside your eyes, a condition called a cataract and you have difficulty reading and seeing in the dark due to oral medication" for health state H (no recurrence with cataract).

The descriptions of 20 hypothetical health states were developed (see Appendix in Supplemental Materials found at http://dx.doi.org/10.1016/j.vhri.2012.03.009 for the English version; the Chinese version is available upon request), including perfect health state, HSw, 12 health states for no recurrence of breast cancer (health states A–L), three for local recurrence (health states M–O), and three for distant recurrence (health states P–R).

Sample characteristics

Of the 33 eligible nurses contacted at the National Cancer Centre Singapore, 4 nurses were involved in the health state description development and were therefore excluded from the interview recruitment, three nurses were on leave, and four nurses declined to participate. Two nurses were further excluded: one nurse did not complete the interview and one was interviewed in Chinese. As such, a total of 20 respondents were included in the analysis. The average time for completion was approximately 75 minutes, ranging from 45 to 95 minutes.

A summary of the respondents' characteristics is shown in Table 1. The majority of the respondents were women (90%), single (50%), and Filipino (45%). Most respondents had completed university education (70%) and had a gross household monthly income between S $1000 and S $2999 (60%). The mean ± SD of age and the years of experience in oncology were 33.2 ± 6.0 and 6.4 ± 3.9 years, respectively.

Table 1 – Characteristics of the study sample.

Characteristics	n (%)
Sex	
Men	2 (10)
Women	18 (90)
Ethnicity	
Filipino	9 (45)
Chinese	7 (35)
Indian	3 (15)
Malay	1 (5)
Highest education level attained	
Secondary	1 (5)
Polytechnic diploma	2 (10)
University degree	14 (70)
Postgraduate degree	1 (5)
Advanced diploma in oncology	2 (10)
Marital status	
Single	10 (50)
Married	9 (45)
Divorced	1 (5)
Gross household monthly income (S $)	
1000–2999	12 (60)
3000–4999	6 (30)
≥5000	2 (10)
Designation	
Staff nurse	11 (55)
Senior staff nurse	5 (25)
Nurse clinician	2 (10)
Others	2 (10)
Age (y), mean ± SD	33.2 ± 6.0
Years of experience in oncology, mean ± SD	6.4 ± 3.9

Health state utility values

Table 2 presents the mean and median of the VAS- and SG-derived utility score for the health states assessed. Among the 20 hypothetical health states, the health state with the lowest utility scores was HSw, followed by "no recurrence with ischemic cerebrovascular events" whereas the health state with the highest utility score, after excluding "perfect health," was "no recurrence with no side effect." The mean utility score of "current health" was greater than 0.9 using both VAS and SG procedures. Among the side effects of hormonal therapy that may occur in the no recurrence state, the ones with the greatest utility detriment were pulmonary embolism, spine fracture, and ischemic cerebrovascular events.

Mean VAS raw scores ranged from 0.299 to 0.870. Thirteen respondents considered HSw worse than being dead and placed HSw at the bottom of the VAS (point 0). After recalibration, the mean adjusted VAS-derived utility scores, which anchored by dead (equal to 0) and perfect health (equal to 1), ranged from 0.256 to 0.860, with SDs ranging from 0.09 to 0.28. The VAS-derived utility scores of the distant recurrence health states were consistently lower than those of locoregional recurrence health states. Such a trend, however, was not observed in SG-derived scores.

After recalibration, the mean adjusted SG scores for HSw ranged from −39.0 to 0.6, which indicates great variation in respondents' preference for HSw and a few respondents' strong avoidance of HSw. Among the respondents who rated HSw worse than being dead, three gave a probability (p) of greater than 0.5 for "dead" and it was considerably higher than the probability they gave for most of the other health states assessed; as a result, their adjusted SG scores for most health states were negative values, which also resulted in negative mean adjusted SG scores. As such, the median, but not mean, adjusted SG scores are presented in Table 2.

Discussion

Despite the increasing interest in and application of pharmacoeconomics in Asian countries, well-designed and rigorous utility

Table 2 – Breast cancer health state utility scores.

	VAS score, raw		VAS score, adjusted		SG score, raw		SG score, adjusted
	Mean	Median	Mean	Median	Mean	Median	Median
A: No recurrence with no side effect	0.870	0.900	0.860	0.892	0.678	0.775	0.673
B: No recurrence with hip fracture	0.514	0.500	0.482	0.495	0.504	0.475	0.353
C: No recurrence with wrist fracture	0.508	0.500	0.475	0.495	0.533	0.500	0.386
D: No recurrence with spine fracture	0.411	0.420	0.372	0.367	0.458	0.463	0.383
E: No recurrence with vaginal bleeding	0.725	0.775	0.704	0.761	0.554	0.500	0.473
F: No recurrence with deep vein thrombosis	0.582	0.575	0.554	0.548	0.515	0.475	0.357
G: No recurrence with pulmonary embolism	0.368	0.350	0.329	0.317	0.463	0.475	0.395
H: No recurrence with cataract	0.547	0.500	0.519	0.461	0.519	0.475	0.355
I: No recurrence with ischemic cerebrovascular events	0.299	0.300	0.256	0.257	0.408	0.425	0.289
J: No recurrence with common side effects—musculoskeletal disorder	0.653	0.695	0.629	0.663	0.510	0.500	0.371
K: No recurrence with common side effects—hot flushes	0.749	0.775	0.730	0.761	0.588	0.550	0.520
L: No recurrence with endometrial cancer	0.506	0.520	0.472	0.500	0.501	0.475	0.365
M: New contralateral breast cancer	0.500	0.500	0.468	0.460	0.443	0.425	0.284
N: Locoregional recurrence with no side effects	0.525	0.500	0.491	0.459	0.473	0.438	0.376
O: Locoregional recurrence with side effects—general	0.506	0.525	0.473	0.522	0.438	0.425	0.336
P: Distant recurrence with no side effects	0.438	0.435	0.400	0.369	0.470	0.450	0.371
Q: Distant recurrence with side effects—chemotherapy	0.404	0.460	0.365	0.392	0.458	0.413	0.356
R: Distant recurrence with side effects—hormonal therapy	0.410	0.425	0.370	0.375	0.445	0.413	0.299
Worse health	0.033	0.000	−0.032	−0.053	0.364*	0.500*	−0.160
Current health	0.944	0.995	0.941	0.995	0.916	0.975	0.973

SG, standard gamble; VAS, visual analogue scale.

* From the seven respondents who considered dead worse than the worst health state.

assessment studies remain limited in this region. We hope that the health state descriptions developed in this study, which are available in two language versions and include a large number of combinations of side effects and disease stages, can be applied and further refined in future research that aims to obtain patient or general public utilities for various health outcomes related to breast cancer and its treatment. The utility data obtained can be combined with cost and clinical trial data to compare different treatment strategies for breast cancer, which could assist clinical decision making and, ultimately, produce the best benefits from constrained health resources.

As expected, locoregional and distant recurrence health states obtained lower utility scores than "no recurrence." The side effects ischemic cerebrovascular events, pulmonary embolism, and spine fracture were observed to have the greatest utility detriment. The utility values for ischemic cerebrovascular events were 0.256 (VAS adjusted mean) and 0.289 (SG adjusted median), which were similar to those reported in a systematic review [12]. The low utility score of spine fracture is not surprising because it can affect not only HRQOL but also mobility and functional independence [13], which has a considerable impact as perceived by respondents who are relatively young and in the midst of building up their careers.

Finally, in health states G and I, even though there is no recurrence of breast cancer, ischemic cerebrovascular events and pulmonary embolism are life-threatening side effects, which could explain their low utility scores. Interestingly, the raw utility scores for endometrial cancer and new contralateral cancer fell between 0.443 and 0.506 in both SG and VAS. One may have expected these health states to have received much lower values. Perhaps because respondents were oncology nurses with a mean of 6.4 years of experience, they may have been more accepting of these health states than the general public, similar to the fact that patients often rate health states with higher values than does the general population [14].

The SG, one of the choice-based preference methods, is considered to be the "gold standard" for utility measurement, and it has been shown to be reliable and valid in Singapore and other countries [15–20]. According to the National Institute for Health and Clinical Excellence, the "reference case" dictates that health state utility values have to be obtained via a choice-based method [21]. As such, SG, along with the commonly used VAS, was used in this study. Although the utility scores obtained may vary depending on the methods used [22–25], it has generally been reported that SG usually provides higher utility scores than does VAS [17]. This trend, however, was not consistently observed in this study. In addition, illogical responses were observed in several nurses who valued "dead" considerably higher than most of the other health states assessed in SG. The reason for these findings remains unclear, but it may be partially explained by respondents' strong avoidance of HSw when compared with being dead. Also, the cognitive ability and abstract thinking required by SG may be demanding, and a few side effects could have been difficult for these young nurses to relate to despite their experience in oncology.

There was only one interviewer involved in this study, and therefore inconsistency in interview administration was kept to a minimum. There are, however, a few limitations to this study. First, the study sample size is small. Nevertheless, there is currently no consensus on sample size requirement for utility assessment, and significant variation in sample size was seen in previous studies in oncology [26]. In addition, because of pragmatic concerns and to avoid descriptions reflecting idiosyncratic varia-

tion, the health states and their descriptions were developed by literature review and expert opinions without patients' direct input. The validity of health state descriptions could have been improved if patients who had experienced the health states had been interviewed. Finally, the utilities obtained from nurses in our study may not reflect societal preferences. It has been suggested that utilities are best obtained from the general population and from patients when clinical decisions are involved [12]. Previous research has tried to investigate whether utilities would differ on the basis of the study population, that is, patients versus general public or health care professionals [27–30]; however, results have been conflicting and inconclusive.

Conclusions

The study results indicate the value that individuals place on the avoidance of disease progression and side effects of hormonal therapies in breast cancer. The health state descriptions developed can be used in future research to obtain society's utilities for use in a cost-utility analysis.

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Supplemental Materials

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